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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
PAK, YONG D	

ART UNIT	PAPER NUMBER
1652	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/744,527	BOUGUELERET, LYDIE	
	Examiner	Art Unit	
	Yong Pak	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 August 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,10,15,21,24-28,32 and 39-68* is/are pending in the application.

4a) Of the above claim(s) *1,10,15,21,24-28,32 and 39-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *43-68f* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

This application is a 371 of PCT/IB99/01353. A preliminary amendment filed on May 9, 2001, amending claims 1, 10, 15, 21, 24-28, 32, 38-41, canceling claims 2-9, 11-14, 16-20, 22, 23, 29-31 and 33-37 and adding claim 42, has been entered. A preliminary amendment filed on August 23, 2001, canceling claim 38 and adding claims 43-68, has been entered.

Claims 1, 10, 15, 21, 24-28, 32, 39-68 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 10, 15, 21, 24-27 and 42, drawn to DNA, vectors, host cells, methods of making polypeptides.

Group II, claim(s) 28-32, drawn to methods of genotyping.

Group III, claim(s) 43-68, drawn to polypeptides of SEQ ID NO:4.

Group IV, claim(s) 39, drawn to antibodies.

Group V, claim(s) 40-41, drawn to methods of screening.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking I-V appears to be that they all relate to a geranylgeranyl pyrophosphate synthetase (GGPPSASE).

Groups I-V do not share a technical feature because the DNA molecule of Group I (claim 1) can encode a polypeptide not having the structure of the protein of Group III. For a DNA and protein group to share a special technical feature, claims drawn to the DNA must be DNA sequences that encode the structure of the protein in the claims drawn to the protein (see PCT administrative instructions Example 17). Therefore, the technical feature linking Group I and Groups II-V is lacking.

During a telephone conversation with Mr. Lucas on August 21, 2001 a provisional election was made with traverse to prosecute the invention of Group I (canceled claim 38 and newly added claims 43-68. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1, 10, 15, 21, 24-28, 32 and 39-42 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 43-68 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 43-68 are drawn to a composition comprising 6, 10, 20 50 or 100 contiguous amino acids of SEQ ID NO:4 where in the contiguous span includes Phe at position 204, Cys at position 205, a Pro at position 225 and a Phe at position 295. Therefore, these claims are drawn to a genus of polypeptides, with any structure and from any source.

The specification does not contain any disclosure of the structure and function of all geranylgeranyl pyrophosphate synthetase (GGPPSASE) fragments or portions of SEQ ID NO:4. The genus of polypeptides that comprise these fragments and portions of GGPPSASE is a large variable genus with the potentiality of encoding many different proteins. Further, a description of only 10, 20, 50 and 100 amino acids, which represent 3%, 7%, 17% and 33%, respectively, of the whole structure of SEQ ID NO:4, amount to

insufficient description of the structure of the polypeptides in this claim. Therefore, these claims are drawn to a large variable genus of DNA molecules encoding polypeptides having unknown activity or inactive variants with an insufficient limitation on structure. Therefore, many structurally and functionally unrelated polypeptides are encompassed within the scope of these claims, including partial amino acid sequences. The specification fails to describe any other representative species by any identifying characteristics or properties or the "functionality" of the polypeptides and fails to provide any structure: function correlation present in all members of the claimed genus.

Therefore, the specification is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Claims 43-68 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the GGPPSASE of SEQ ID NO:4, does not reasonably provide enablement for fragments of SEQ ID NO:4 of unknown structure and function. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, how to make the invention commensurate in scope with these claims.

Factors to be in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art,

(7)considered in determining whether undue experimentation is required, are summarized the predictability or unpredictability of the art, and (8) the breadth of the claims.

The claims are drawn to polypeptides comprising fragment or portions of SEQ ID NO:4 having GGPPSASE or unknown activity. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of constructs broadly encompassed by the claims.

The specification does not teach how to make polypeptides with structures different from SEQ ID NO:4 having GGPPSASE activity. Applicants do not teach which amino acids of SEQ ID NO:4 can be modified without affecting the functional properties of the polypeptide. The specification does teach how to make variants of SEQ ID NO:4 having unknown function. However, the function of a polypeptide can not be predicted from its structure and the specification does not teach how to use polypeptides with unknown function. Therefore, the breadth of these claims is much larger than the scope enabled by the specification.

While recombinant techniques are available, it is not routine in the art to screen large numbers of amino acids where the expectation of obtaining similar sequences is unpredictable. The amino acid sequence determines the structural and functional properties of an enzyme. Knowledge of which sequences can be altered or removed and still result in similar protein activity is well outside the realm of routine experimentation.

The specification, which places no limitation on the structure of the polypeptides as discussed above, does not support the broad scope of the claims because the

specification does **not** establish: (A) regions of the GGPPSASE structure which may be modified without effecting its activity; (B) the general tolerance of to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Therefore, one of ordinary skill would require guidance in order to make polypeptides with structures different from SEQ ID NO:4 having GGPPSASE activity and how to use variant polypeptides of SEQ ID NO:4 having unknown function in a manner reasonable correlated with the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 43-68 are rejected under 35 U.S.C. 102(b) as being anticipated by Greene et al. (WO 96/21736).

Green et al. (WO 96/21736 – form PTO-1449) teach a composition comprising a polypeptide that is 100% identical to SEQ ID NO:4 of the instant invention (Figure 3 – human –GGPS sequence). Regarding claims **43-48**, the composition of Greene et al. comprises of at least 6, 10, 20, 50 and 100 contiguous amino acids of SEQ ID NO:4 and includes a Phe residue at position 204. Regarding claims **43 and 49-53**, the composition of Greene et al. comprises of at least 6, 10, 20, 50 and 100 contiguous amino acids of SEQ ID NO:4 and includes a Phe residue at position 295. Regarding claims **43 and 54-58**, the composition of Greene et al. comprises of at least 6, 10, 20, 50 and 100 contiguous amino acids of SEQ ID NO:4 and includes a Cys residue at position 205. Regarding claims **43 and 59-63**, the composition of Greene et al. comprises of at least 6, 10, 20, 50 and 100 contiguous amino acids of SEQ ID NO:4 and includes a Pro residue at position 225. Regarding claims **43 and 64-67**, the composition of Greene et al. comprises of at least 6, 10, 20, 50 and 100 contiguous amino acids of SEQ ID NO:4 and includes Phe residue at position 257. Therefore, the teachings of Greene et al. anticipates claims 43-68.

Claims 43-68 are rejected under 35 U.S.C. 102(e) as being anticipated by Greene et al. (U.S. Patent 5,786,193).

Green et al. (U.S. Patent 5,786,193– form PTO-1449) teach a composition comprising a polypeptide that is 100% identical to SEQ ID NO:4 of the instant invention

(Figure 3 – human GGPS sequence). Regarding claims **43-48**, the composition of Greene et al. comprises of at least 6, 10, 20, 50 and 100 contiguous amino acids of SEQ ID NO:4 and includes a Phe residue at position 204. Regarding claims **43 and 49-53**, the composition of Greene et al. comprises of at least 6, 10, 20, 50 and 100 contiguous amino acids of SEQ ID NO:4 and includes a Phe residue at position 295. Regarding claims **43 and 54-58**, the composition of Greene et al. comprises of at least 6, 10, 20, 50 and 100 contiguous amino acids of SEQ ID NO:4 and includes a Cys residue at position 205. Regarding claims **43 and 59-63**, the composition of Greene et al. comprises of at least 6, 10, 20, 50 and 100 contiguous amino acids of SEQ ID NO:4 and includes a Pro residue at position 225. Regarding claims **43 and 64-67**, the composition of Greene et al. comprises of at least 6, 10, 20, 50 and 100 contiguous amino acids of SEQ ID NO:4 and includes Phe residue at position 257. Therefore, the teachings of Greene et al. anticipates claims 43-68.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on 8:00 A.M. to 4:30 P.M weekdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong Pak
Patent Examiner

September 24, 2002

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